IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

FRESENIUS KABI USA, LLC, Plaintiff, vs. STATE OF NEBRASKA; THE NEBRASKA DEPARTMENT OF CORRECTIONAL SERVICES; and SCOTT FRAKES, in his Official Capacity as Director of the Nebraska Department of Correctional Services, Defendants.	CASE NO. 4:18-cv-03109

BRIEF IN SUPPORT OF PLAINTIFF'S MOTION FOR TEMPORARY RESTRAINING ORDER AND EXPEDITED DISCOVERY AND MOTION FOR PRELIMINARY INJUNCTION

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Plaintiff, Fresenius Kabi, USA, LLC ("Fresenius Kabi"), submits this brief in support of its Motions for Temporary Restraining Order and for Preliminary Injunction.

I. BACKGROUND

Defendants intend to execute Carey Dean Moore by lethal injection on August 14, at 10:00 a.m. [Compl. Ex. A]. Only three weeks ago, Fresenius Kabi learned through publicly disclosed records that one, possibly two, of the drugs Defendants will use for this execution were manufactured by Fresenius Kabi. [Declaration of John Ducker ("Ducker Decl."), ¶ 3]. Through a public-records request, the Defendant Nebraska Department of Correctional Services ("NDOC") disclosed its inventory of potassium chloride ("KCL") and cisatracurium besylate ("Cisatracurium"). [Compl. Exs. D, E; Declaration of Amy Miller ("Miller Decl."), Ex. A, Ex. B at p. 28, Ex. C., and Ex. D at p. 12]. The inventory for KCL discloses Defendants possess 25 units (vials) of 30 milliliters each in a concentration of 2 mEq/mL. [Compl. Exs. D, E]. Fresenius Kabi is the only manufacturer of which it is aware that sells KCL for intravenous injection in 30 milliliter vials in that concentration. [Ducker Decl., ¶ 4, Ex. A].

Defendants could only have acquired this drug in contravention of Fresenius Kabi's tight supply-chain controls intended to prevent correctional facilities from acquiring KCL. [Ducker Decl. ¶ 6, Ex. D; Declaration of Jack Silhavy ("Silhavy Decl."), ¶ 6—7, Ex. A, B]. On July 24, President and CEO of Fresenius Kabi, John Ducker, wrote to Governor Pete Ricketts explaining the life-saving purpose of Fresenius Kabi's products, the harm that would occur from

a shortage of those drugs, the supply-control measures Fresenius Kabi employs to effect those purposes, and the illegal and improper nature of Defendants' procurement. [Ducker Decl. ¶ 6, Ex. D]. President Ducker demanded that Defendants "immediately disclose the quantities, lot numbers, inventory logs, and invoices for any Fresenius Kabi drugs the state may have acquired for executions, and that you return any such drugs to us without delay. We will provide a full refund." [Id.] Copies of the letter were sent to Defendant Frakes and Nebraska Attorney General Doug Peterson. [Id.] Fresenius Kabi has not received a substantive response from Defendants[1] and so has initiated this action. [Ducker Decl. ¶ 7].

Fresenius Kabi now seeks emergency injunctive relief to prevent the imminent and irreparable harm it will suffer if Defendants are permitted to use its drugs in the execution of Carey Dean Moore.

A. The Two Medicines At Issue: Potassium Chloride and Cisatracurium Besylate

In January 2018, Defendant Frakes notified Moore that he would be executed by lethal injection using a four-drug sequence: Diazepam; Fentanyl Citrate; Cisatracurium Besylate; and Potassium Chloride. NDCS Provides Notice of Substances to be Employed in an Execution by Lethal Injection, NEB. DEP'T OF CORRECTION SERVS. (Jan. 19, 2018), https://corrections.nebraska.gov/ndcs-

[1] In a letter dated July 31, and mailed August 1, an administrative assistant in Governor Ricketts' office replied with a letter explaining that it construed President Ducker's remand as a public records request and that the Governor's office did not have custody of those records.

provides-notice-substances-be-employed-execution-lethal-injection-0. Fresenius Kabi manufactures the third and fourth drugs on this list.

KCL is a federally regulated substance tested and approved by the Food and Drug Administration ("FDA") for certain legitimate medical and nonmedical purposes, such as the treatment of potassium deficiency. [Silhavy Decl , ¶¶ 5, 7; [Declaration of Scott Meacham ("Meacham Decl."), ¶ 6]. Execution by lethal injection is not a purpose for which it is approved or a use for which it is intended. [Silhavy Decl , ¶¶ 5, 7].

Fresenius Kabi also manufactures Cisatracurium. [Silhavy Decl , ¶¶ 5, 7]. The fact that Defendants have engaged in measures to circumvent Fresenius Kabi's distribution control to obtain KCL raises the very real concern that the Cisatracurium in Defendants' inventory was also manufactured by Fresenius Kabi. There are only three firms that sell Cisatracurium in the United States. [Silhavy Decl., ¶ 10]. Cisatracurium, too, is tested and approved by the FDA for certain uses that do not include lethal injection. [Silhavy Decl., ¶¶ 5, 7]. Such legitimate purposes include use as a neuromuscular relaxant for use in major surgical procedures. [Meacham Decl., ¶ 9]. Importantly, Cisatracurium is to be maintained at a temperature of 34 to 46 °F in carton to preserve its potency. [Id.] Defendants' execution protocol directs that the drugs in their possession be maintained under "room temperature storage conditions." 69 Neb. Admin. Code § 11-008.04.

B. Fresenius Kabi's Distribution Controls

Although Fresenius Kabi does not take a position on capital punishment, it has made a business judgment that its interests are best served by exercising certain controls over the distribution of its products and seek to prevent its medications from being used in lethal injection executions. [Meacham Decl., ¶¶ 12—17; Declaration of Joachim Weith ("Weith Decl."), ¶ 4—16]. Drugs listed on Fresenius Kabi's Schedule of Restricted Products may only be sold to Authorized Distributors which have contractually agreed to particular constraints. [Silhavy Decl , ¶ 6]. The distribution agreements Fresenius Kabi enters into with its Authorized Distributors ("AD") contain the following, or substantially similar, language:

> Own use. [AD] agrees to sell the Restricted Products only to end user customers and on the condition that the Restricted Products are solely for administering to their respective patients. Accordingly, [AD] shall not sell the Restricted Products to any other wholesaler, distributor, retailer or other re-seller, including [AD]'s subsidiaries and affiliates, and shall instruct any customers to whom Restricted Products are sold, including [AD]'s subsidiaries and affiliates, that they may not sell or otherwise transfer the Restricted Products to any wholesaler, distributor, retailer, institution or any third party.
>
> Excluded Customers. [AD] shall (i) implement the steps necessary in it systems and processes to ensure that [AD] does not sell the Restricted Products to federal or state prisons, penitentiaries, jails or other incarceration facilities ("Excluded Customers"); (ii) not sell or distribute the Restricted Products, directly or indirectly, to Excluded Customers, whether within or outside the Territory; (iii) inform its customers that the Restricted Products may not be re-sold or distributed to Excluded Customers; and (iv) immediately notify Supplier in writing if [AD] learns that a customer is, directly or indirectly, marketing, selling or distributing Restricted Products to Excluded Customers, or that such customer is assisting any other party to do so, and in such event, [AD] shall

> immediately cease supplying the Restricted Product to such customer.

[Silhavy Decl., Ex. A]. Both KCL and Cisatracurium are on Fresenius Kabi's Schedule of Restricted Products. [Silhavy Decl., ¶ 7].

As set out below, there are several reasons Fresenius Kabi has determined that the potential harm to its reputation among its customers, to its business and investment relationships, to its finances and other commercial interests, *and most importantly to the well being of the end users of its life-saving products*, demand these tight controls.

First, Fresenius Kabi's customers—largely medical professionals including physicians and pharmacists—are members of organizations that have uniformly adopted policies disavowing any association between their respective professions and capital punishment. [Meacham Decl., ¶ 12]. Such organizations include the American Medical Association, the American Society of Anesthesiologists, the American Board of Anesthesiology, Inc., the American Nursing Association, the American Pharmacists Association, the American Public Health Association, the International Academy of Compounding Pharmacists, and the American College of Physicians. [Compl. Exs. G–O].

Second, Fresenius Kabi is the American affiliate of Fresenius SE & Co. KGaA ("Fresenius SE"), a German manufacturer of medicines and medicine technologies that are distributed and used throughout the world. [Weith Decl., ¶ 3]. Because capital punishment is viewed negatively among the European public, the European Commission (the governing body of the European Union) has promulgated and implemented regulations restricting the export of products that

"could be" used for carrying out executions, even when those products have other uses. [Weith Decl., ¶¶ 4, 7, 8; Weith Decl., Ex. A]. Once such a product has been identified, it may only be exported if granted an "Export Authorization." [Weith Decl., ¶ 8, 10]. Such authorization is denied if there are reasonable grounds to believe the product might be used for capital punishment. [Id.]

Obviously, the risk that other of its products that are manufactured in Europe may be subject to export restrictions is a serious concern. [Weith Decl., ¶ 16]. Such a restriction would have a significant negative effect not only on Fresenius SE's financial health and other commercial interests, but such effects would flow to its associated companies, including Fresenius Kabi. [Id.; Meacham Decl. ¶ 15]. This risk has already arisen specifically with respect to a product, propofol, which it sells under the Diprivan® brand name. [Weith Decl., ¶¶ 5–16].

Third, Fresenius Kabi's first priority is the supply of these medicines for legitimate medical purposes. [Ducker Decl. ¶ 5, Ex. C; Meacham Decl., ¶¶ 6, 9]. KCL in injectable form is listed on the FDA's Drug Shortages List, and its current status is listed as "Currently in Shortage." FDA Drug Shortages, U.S. FOOD & DRUG ADMIN. (last visited Aug. 6, 2018), https://www.accessdata.fda.gov/scripts/drugshortages/. As a supplier of KCL and Cisatracurium, Fresenius Kabi is concerned that the procurement of these products by States for non-FDA-approved uses will result in shortages for end users of the medicines it manufactures. [Ducker Decl. ¶ 5, Ex. C].

Fourth, there is the threat among both United States and European investors of divestment from manufactures of pharmaceutical products that are

used in lethal injections. For example, the New York State Common Retirement Fund ("NYSCRF")—the third largest public pension plan in the country, valued at over $200 billion, which currently holds $1.8 million in investments in Fresenius SE—passed a shareholder resolution in 2015. DiNapoli: Pharma Company Agrees to Bar Its Drugs From Use in State Executions, NEWS FROM THE OFFICE OF THE NEW YORK STATE COMPTROLLER (March 04, 2015), https://www.osc.state.ny.us/press/releases/mar15/030415.htm. That resolution threatened to divest $14.5 million from Akorn Pharmaceuticals because of insufficient measures to prevent its products from being used in lethal injections. Id. After Akorn took action to implement tighter distribution controls, the resolution was withdrawn. NYSCRF implemented a similar resolution with respect to Mylan, another drug manufacturer. Id. DJE Kapital, a German asset manager, sold its $70 million worth of holdings in Mylan because of the use of its paralytic, rocuronium bromide, in lethal injections. Drug Maker Mylan Takes $70 Million Hit in Battle Over Lethal Injection, NBC NEWS (Oct. 21, 2014), https://www.nbcnews.com/storyline/lethal-injection/drug-maker-mylan-takes-70-million-hit-battle-over-lethal-n230051; Ty Alper, Why the Execution Drug Shortage Won't Go Away, LA TIMES (Apr. 13, 2015), http://www.latimes.com/nation/la-oe-alper-lethal-injection-shortages-20150414-story.html ("As the investment firm DJE Kapital stated in 2014 when it divested $70 million from Mylan, which produces the paralytic agent used in some lethal injection executions, 'If clients find out we have shares in companies that supply that drug, we have problems with our clients.'"). Unipension, a $15

billion pension fund, sold its 300,000 shares in Lundbeck, a Danish manufacturer of penobarbital, a drug used in lethal injections, because of its refusal to tighten its distribution of the drug. Andrew Jack, Fund Sells Lundbeck Stake Over Death Row Drug, FINANCIAL TIMES (May 13, 2011), https://www.ft.com/content/ff00a5f8-7d93-11e0-b418-00144feabdc0; [Declaration of Nathan Clark ("Clark Decl."), Ex. A]. As reported in the *New York Times*:

> Pressure on the drug companies has not only come from human rights groups. Trustees of the New York State pension fund, which is a major shareholder in Pfizer and many other producers, have used the threat of shareholder resolutions to push two other companies to impose controls and praised Pfizer for its new policy.

Pfizer Blocks the Use of Its Drugs in Executions, THE NEW YORK TIMES (May 13, 2016), https://www.nytimes.com/2016/05/14/us/pfizer-execution-drugs-lethal-injection.html. NYSCRF has submitted shareholder proposals to two of Fresenius Kabi's Authorized Distributors—McKesson Corporation and Cardinal Health—seeking reports on how those companies control the distribution chain of their products that may be used in lethal injections. McKesson Corp., SEC No-Action Letter, 2017 WL 11191884 (June 1, 2017); [Clark Decl., Exs. B, C].

Finally, drug manufacturers are subject to potential liability when their products are used in botched executions. For example, Hospira, Inc., and McKesson Corp., both distributors of drugs used in the botched execution of Dennis McGuire in Ohio in 2014, were sued in the U.S. District Court for the Southern District of Ohio on products liability and other theories. See McGuire

v. Mohr, First Amended Complaint, No. 2:14-cv-00093, 2014 WL 7335909 (Dec. 5, 2014).

C. Defendants' Have Knowingly Thwarted Fresenius Kabi's Distribution Controls

Defendants have knowingly disregarded and circumvented these controls, and they have done so in the past. Fresenius Kabi has repeatedly communicated to the Defendants its restrictions it places on its distributors. In 2015, Cardinal Health, one of Fresenius Kabi's Authorized Distributors, erroneously delivered KCL to the NDCS.[2] [Meacham Decl., ¶¶ 18, 19]. A Cardinal sales representative twice asked the pharmacist in charge at the NDCS to have the product returned. [Id.]. NDCS refused, stating that the KCL *would only be used to treat patients.* [Id.]. In December 2016, the President of Fresenius Kabi, John Ducker, wrote to legal counsel for NDCS, noting that he had become aware of Nebraska's proposed revision to its lethal-injection protocol. [Ducker Decl. ¶ 5, Ex. C]. He expressed concern that Fresenius Kabi's products may be used in an execution, explaining that "[t]his would be an improper use of these products, which are intended to save lives." [Id.]. He concluded, "As Nebraska works to revise it execution protocol, I am asking for your assurance that Nebraska will not use Fresenius Kabi medicines as execution agents . . . ." [Id.].

Despite this admonition, and as described above, Fresenius Kabi has recently learned that Defendants appear to have in their possession KCL manufactured by it. After the above-described letter to Governor Ricketts went

[2] These were different units of KCL than the KCL at issue in this suit.

substantively unanswered, Fresenius Kabi initiated this action to seek the return of its product and an injunction from Defendants using its products for lethal injection in the future.

II. ARGUMENT

Defendants' wrongful possession of Fresenius Kabi's drugs threatens a tortious interference with its current and future business relationships and expectancies; is an ongoing and threatened transgression of Fresenius Kabi's possessory and use rights in its drugs; violates the Interstate Commerce Clause; and threatens to deprive Fresenius Kabi of due process. These threatened harms cannot be repaired by damages, due to their immeasurable and therefore noncompensable nature, and they constitute real, tangible harms that vastly outweigh the State's interest in executing Moore with these particular drugs next week. Further the public interest is served by the transparent, regulated distribution of these drugs, which Fresenius Kabi seeks to forward and Defendants seek to avoid.

A. Standard for Temporary Restraining Order and Preliminary Injunction

"In deciding whether to issue a preliminary injunction, the district court should consider '(1) the threat of irreparable harm to the movant; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest." Enerplus Resources (USA) Corp. v. Wilkinson, 865 F.3d 1094, 1097 (8th Cir. 2017) (quoting Dataphase Sys., Inc. v. C L Sys., Inc., 640 F.2d 109, 113 (8th Cir. 1981) (en banc)). In making this

determination, "No single factor is dispositive, as the district court must balance all factors to determine whether the injunction should issue." United Indus. Corp. v. Clorox Co., 140 F.3d 1175, 1179 (8th Cir. 1998).

In determining whether to grant a motion for temporary restraining order, district courts in this circuit look to the same four factors. See, e.g., Rodgers v. Bryant, 301 F. Supp. 3d 928, 936 (E.D. Ark. 2017); Medtronic, Inc. v. Ernst, 182 F. Supp. 3d 925, 934 (D. Minn. 2016); Gahan ex rel. Gahan v. U.S. Amateur Confederation of Roller Skating, 382 F. Supp. 2d 1127, 1129 (D. Neb. 2005).

B. Fresenius Kabi Will Suffer Harm to its Reputation, Goodwill, and Business Relationships

"It is well established that '[i]rreparable harm occurs when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages.'" Grasso Enterprises, LLC v. Express Scripts, Inc., 809 F.3d 1033, 1040 (8th Cir. 2016). "Loss of intangible assets such as reputation and goodwill can constitute irreparable injury." United Healthcare Ins. Co. v. AdvancePCS, 316 F.3d 737, 741 (8th Cir. 2002). This Circuit has affirmed a preliminary injunction where the nonmovant's conduct threatened to "erode[] consumer confidence," noting that "[h]arm to reputation and goodwill is difficult, if not impossible, to quantify in terms of dollars." Medicine Shoppe Int'l, Inc. v. S.B.S. Pill Dr., Inc., 336 F.3d 801, 805 (8th Cir. 2003). Such irreparable harm also includes injury to the movant's business relationships. See Am. Express Fin. Advisors, Inc. v. Yantis, 358 F. Supp. 2d 818, 835 (N.D. Iowa 2005) ("Intangible injuries, such as injury to goodwill and

business relationships with customers, may be found to constitute irreparable harm.").

The United Healthcare case is illustrative of the threatened injury here. AdvancePCS administered a drug discount program for the AARP, but that relationship was terminated. 316 F.3d at 740. AdvancePCS, using information it had previously gathered from AARP members, launched a competing program. Id. This Court affirmed the district court's grant of a preliminary injunction without a hearing. Id. at 745.

One of the threatened harms in United Healthcare arose because AdvancePCS was using past information that may not have accurately reflected AARP members' updated prescription-medication history, giving rise to the risk of an adverse drug reaction. Id. at 741. Because AARP members "could reasonably be expected to attribute shortcomings in their prescription history to AARP," "[t]he district court found that an adverse drug reaction resulting from an incomplete [patient information] may irreparably harm AARP's reputation and goodwill among its members." Id.

The Eighth Circuit affirmed. Noting the loss of intangible assets may constitute irreparable harm, it concluded there was a "sufficiently high probability" that AARP members would attribute shortcomings in their history to that organization. Id. at 742. It rejected the argument that the potential for adverse drug reactions was too speculative, even though there was no evidence of complaints of an adverse drug reaction. Id. The court stated:

> [W]e do not find the lack of complaints to be dispositive of the issue, as it might take months for a loss of goodwill to become manifest.

> Indeed, AARP Program participants have no reason to know that their prescription history may be inaccurate given AdvantagePCS's secretive manner of processing claims.

Id.

Similarly, Fresenius Kabi faces the imminent threat of noncompensable injury to its goodwill, reputation, and business relationships among its customers, its investors, its end users, and to the public at large who are all potential end users of Fresenius Kabi's products. As described, Fresenius Kabi's customers are members of professional organizations that universally reject their association with lethal injection. Obviously, in a competitive market, Fresenius Kabi's reputation among its customers bears directly on its current and future revenues. [Meacham Decl. ¶ 13]. If Fresenius Kabi had a demonstrated inability to effect strict controls over its product, customers may factor this in to their decision about whether to turn to other manufacturers.

In addition, investors in Fresenius Kabi's publicly traded parent, Fresenius SE's, in the United States and Europe may engage in the same divestment strategies that have been documented with so many other manufacturers and suppliers of drugs that are used, or may be used, in lethal injections. As documented above in media reports cited in Section I of this brief, the NYSCRF has exercised its power as an investor repeatedly to introduce shareholder resolutions requiring the disclosure of distribution controls over drugs that may be used in lethal injections. These have recently included Fresenius Kabi's Authorized Dealers Cardinal Health and McKesson Corporation. NYCSCRF and other investors have threatened to divest, or actually divested, millions of dollars

in investments in manufacturers they believe do not exercise strict enough controls over their products. Defendants' actions present a real risk Fresenius SE may subject to the same divestment strategies.

There is also a real threat to Fresenius Kabi's reputation from a botched execution. As noted above, Defendants' protocol calls for room temperature storage of Cisatracurium, a substance which should be stored at 34 to 46 °F. Further, Fresenius Kabi is not aware of any other state that has ever implemented a lethal-injection protocol with this particular combination of drugs. See Current State-By-State Execution Protocols, LETHAL INJECTION INFORMATION CENTER (last visited Aug. 7, 2018) (listing lethal-injection protocols from all applicable states), http://lethalinjectioninfo.org/lethal-injection-protocols/. As noted, the drugs at issue were tested and designed for the purpose of treating patients, and have never been designed or tested for use in causing death.

A botched execution would compound the risk of divestment and cause Fresenius Kabi reputational harm among its investors, customers, and end users. Such events have been widely reported in the media, see, e.g., Jeffrey Stern, The Cruel and Unusual Execution of Clayton Lockett, THE ATLANTIC (June 2015), available at https://www.theatlantic.com/magazine/archive/2015/06/execution-clayton-lockett/392069/, and there is at least a "sufficiently high probability" that the public would associate such an event with the manufacturer of that product, especially given the "secretive" nature of Nebraska's procurement of these drugs.

Further, a botched execution would expose Fresenius Kabi to the risk of liability from the executed inmate's estate. Although such liability may one day be expressed in dollars and cents, the associated harm to reputation, goodwill, and investment from a publicized law suit would not be. See Otter Prod., LLC v. United States, 37 F. Supp. 3d 1306, 1315 (Ct. Int'l Trade 2014) ("[T]he ability to calculate a financial loss may not preclude a finding of irreparable harm, because accompanying harm from '[p]rice erosion, loss of goodwill, damage to reputation, and loss of business opportunities' may be irreparable." (quoting Kwo Lee, Inc. v. United States, 24 F. Supp. 3d 1322 (Ct. Int'l Trade 2014)).

Finally, Fresenius Kabi's reputation and goodwill will be harmed by any shortages that result from Defendants' use of KCL and Cisatracurium in an execution. If successful, other states may follow suit, see Deborah W. Denno, Lethal Injection Chaos Post-Baze, 102 GEO. L.J. 1331, 1357–58 (2014) ("For over a century, states have closely followed the execution strategies of other states . . . ."), risking a shortage of those products for legitimate uses for which they were designed. As mentioned above, KCL is on the FDA's list of drug shortages. FDA Drug Shortages List, supra. There again is a sufficiently high probability that the end-using public, affected by these shortages, would associate it with the use of Fresenius Kabi's drugs in lethal executions.

C. The Balance of Harms Weighs Heavily in Favor of Fresenius Kabi

Next, the court "must balance this harm with any injury an injunction would inflict on other interested parties." Richland/Wilkin Joint Powers Auth. v. U.S. Army Corps of Eng'rs, 826 F.3d 1030, 1040 (8th Cir. 2016). Fresenius Kabi

has demonstrated how it faces impossible-to-quantify injury to its goodwill, reputation, and business relationships among its customers, investors, end users, and the public at large if its life-saving drugs are used in lethal injections. This harm greatly outweighs the injury, if any, to be inflicted on Defendants for several reasons.

First, the requested temporary restraining order and injunction will not bar Defendants' efforts to put inmates to death. Nebraska statutes and the Nebraska Department of Correctional Services' Execution Protocol permit the Director to perform lethal injections using drugs other than those manufactured by Fresenius Kabi. NEB. REV. STAT. § 83-965(2)(a)–(b); 69 Neb. Admin. Code § 11-008.02, § 11-008.03. Simply put, Defendants may fulfill their legal obligations and carry out the Court's death sentence even if the order and injunction are granted.

Second, the Defendants are not injured by a potential delay in carrying out the Court's death sentence. Moore is the state's longest-serving death row inmate. Defendants have not conducted an execution since 1997. They have never conducted an execution by lethal injection. They now attempt to be the first in the U.S. to utilize an untested four-drug execution protocol, which involves risks of a botched execution and potential civil liability, and which Moore's current attorney believes he has an ethical obligation to challenge. Duggan, Joe, *Lawyer for condemned inmate Carey Dean Moore wants off the case just days before execution*, Omaha World Herald (Aug. 7, 2018), https://www.omaha.com/news/courts/lawyer-for-condemned-inmate-carey-

dean-moore-wants-off-the/article_6360069a-336b-583e-8d3c-e30b7fb143cc.html. Defendants will not be injured by waiting longer to identify a method to put inmates to death that has been tested, approved by the Courts, and does not utilize drugs that have been acquired through secret, improper, or illegal means.

Third, Defendants' interests bear no urgency where the delay is of their own making. Fresenius Kabi has opposed the use of its products in connection with lethal injections and placed accompanying contractual supply chain controls on its products since at least 2012. Defendants are well aware that Fresenius Kabi opposes the use of its drugs as part of any state's lethal-injection protocol. Defendants have been aware that Fresenius Kabi specifically opposes the use of its drugs for the purpose of carrying out executions in Nebraska due to prior correspondence between the parties on December 27, 2016 (relating to a prior improper acquisition of Fresenius Kabi's products by Defendants in 2015) and July 24, 2018. If Defendants wished to litigate the propriety of using the Fresenius Kabi products they held in inventory, they had ample time to do so. Moreover, they were the only parties in a position to do so.

Any urgency with respect to this action is due to the Defendants' efforts to shield their actions from the view of the public and manufacturers like Fresenius Kabi. Prior to November 2017, Defendants had never taken the position that the identity of a drug manufacturer or supplier was not a matter of public record. But currently, they are appealing an Order from the District Court of Lancaster County requiring them to release information regarding how and from whom

they acquired the drugs at issue in this case. Due to the actions of Defendants, Fresenius Kabi had to rely on an inventory list produced in the Lancaster County litigation, its own knowledge of its product line, and its knowledge of comparable products in the industry to determine that Defendants had improperly acquired its drugs and intended to use them in the execution of Moore. Once it learned of this information, Fresenius Kabi took prompt action to assert its rights. The same cannot be said for Defendants. Any argument that Defendants would be harmed by the requested injunction because of their legal obligations to carry out executions or a delay in carrying out Moore's execution is meritless. The balance of the harms greatly favors Fresenius Kabi.

D. Fresenius Kabi Has A Fair Chance of Succeeding On the Merits of Its Claims

The next factor the court must consider is the moving party's probability of success on the merits. "[W]here the balance of other factors tips decidedly toward plaintiff a preliminary injunction may issue if movant has raised questions so serious and difficult as to call for more deliberate investigation." Dataphase Sys., Inc. v. C L Sys., Inc., 640 F.2d 109, 113 (8th Cir. 1981). Importantly, in cases of this type—where the challenged action is *not* the implementation of a state statute—the moving party is required to show only a "fair chance" of prevailing on the merits, rather than show it is "likely" to. Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds, 530 F.3d 724, 732 (8th Cir. 2008). Moreover, if the moving party has asserted multiple claims, it need only establish a probability of success on one of them.

Richland/Wilkin, 826 F.3d at 1040 (quoting Am. Rivers v. U.S. Army Corps of Eng'rs, 271 F. Supp. 2d 230, 250 (D.D.C. 2003)).

1. Fresenius Kabi Has a Fair Chance of Success on Its Claim of Tortious Interference with Prospective Business Relations

The elements for a claim for tortious interference with business relations in Nebraska are:

> (1) the existence of a valid business relationship or expectancy, (2) knowledge by the interferer of the relationship or expectancy, (3) an unjustified intentional act of interference on the part of the interferer, (4) proof that the interference caused the harm sustained, and (5) damage to the party whose relationship or expectancy was disrupted.

Thompson v. Johnson, 299 Neb. 819, 828, 910 N.W.2d 800, 806–07 (2018). Fresenius Kabi, as a nationwide supplier of pharmaceutical products, has valid business relationships, and expectations of future ongoing business relations, with its distributors and the physicians and pharmacists to whom it ultimately sells its products, as well as its investors. Further, there is no question that based on this action and Fresenius Kabi's earlier correspondence to Defendants, Defendants have knowledge of the threat of interference the Moore execution carries with respect to those business relationships and expectancies. Fresenius Kabi has already discussed the irreparable harm that Defendants' threatened actions pose to its relationships with its customers, investors, and end users.

With respect to whether Defendants' intentional act of executing Moore using Fresenius Kabi's drugs is unjustified, the Nebraska courts have adopted the seven-factor test from the Restatement:

> (1) the nature of the actor's conduct, (2) the actor's motive, (3) the interests of the other with which the actor's conduct interferes, (4) the interests sought to be advanced by the actor, (5) the social interests in protecting the freedom of action of the actor and the contractual interests of the other, (6) the proximity or remoteness of the actor's conduct to the interference, and (7) the relations between the parties.

Sulu v. Magana, 293 Neb. 148, 158, 879 N.W.2d 674, 682 (2016) (citing Restatement (Second) of Torts § 767 (1979)).

Besides reciting these Restatement elements, it is important to highlight certain types of acts that Nebraska courts have found to be "unjustified." Acts that are independently tortious are per se unjustified. W. Plains, L.L.C. v. Retzlaff Grain Co. Inc., No. 8:13CV47, 2016 WL 3387165, at *2 (D. Neb. May 9, 2016), aff'd, 870 F.3d 774 (8th Cir. 2017); Harvey S. Perlman, Interference with Contract and Other Economic Expectancies: A Clash of Tort and Contract Doctrine, 49 U. CHI. L. REV. 61, 78 (1982). As explained below with respect to Fresenius Kabi's replevin claim, Defendants conduct meets this test here.

Unlawful acts count as well. Nebraska execution protocol specifies that "[t]he substance or substances" to be used in a lethal-injection execution "may be directly purchased or obtained through the Department [of Correctional Service] Pharmacy or obtained *through any other appropriate source*, including pharmaceutical or chemical compounding." 69 Neb. Admin. Code § 11-008.03. Although Defendant's secretive acts have prevented Fresenius Kabi or this Court from presently knowing exactly how Defendants procured the KCL and Cisatracurium, there exists the very real possibility—a strong enough possibility

for temporary injunctive relief pending discovery on the topic—that the source was not "appropriate."

In any event, several of the Restatement factors, too, favor a finding that Defendants' use of Fresenius Kabi's drugs in the Moore execution would be unjustified. *First*, the nature of Defendants conduct is surreptitious procurement, evading contractual supply controls and denying Fresenius Kabi the right to deal with whom it wishes. See Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 602 (1985) (recognizing "the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal" (quoting United States v. Colgate & Co., 250 U.S. 300, 307 (1919)). Furthermore, this conduct has as its purpose the use of a scarce and federally regulated substance inconsistent with—indeed diametrically opposed to—its approved and life-saving uses.

Second, the interests that Fresenius Kabi seeks to protect are essential to commerce in an enormously important sector of the economy. Pharmaceutical manufacturers such as Fresenius Kabi provide the means for life-saving treatments that affect virtually every member of society. Without the means to exercise discretion over who these products are sold to, and without the ability to prevent significant harm to its commercial interests through contract, there is a serious risk of drug shortages and financial harm to these firms.

Third, the social interest in protecting the freedom of Defendants to carry out executions is not significantly impaired by recognizing Fresenius Kabi's

contractual interests with its customers and end users. Fresenius Kabi does not seek an injunction any broader than a prohibition on the use of *its products* in Moore's execution.

Fourth, Defendants' conduct would be closely proximate to the harm Fresenius Kabi would suffer in its business relationships. The cessation of contractual relationships between customers or investors would be a direct response to the use of Fresenius Kabi's products in the execution.

Given Defendants' unjustified and knowing behavior, which threatens the cancellation of investor and commercial contracts with Fresenius Kabi, Fresenius Kabi has a fair chance of success on the merits of its tortious interference with business relationships claim.

2. Fresenius Kabi Has a Fair Chance of Success on Its Replevin Claim Because Defendants Wrongfully Possess Their Drugs In Contravention of Fresenius Kabi's Absolute Right to Trade and Without Good Title

Fresenius Kabi's right to immediate possession of the products in question is greater than the Defendants' right to the same and as such Fesenius Kabi is entitled to assert a right of replevin. Fresenius Kabi has the right to place restrictions on those who it will deal with, and Defendants wrongfully possess Fresenius Kabi's products in violation of that right. See Aspen Skiing, 472 U.S. at 602 (recognizing "the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal" (quoting Colgate, 250 U.S. at 307). Fresenius Kabi has exercised this right with respect to downstream purchasers

by only transferring the right to possess and use their products for legitimate medical purposes.

Crucially, *Defendants have not acquired good title to the KCL and Cisatracurium.* As a general rule, those who purchase goods but "who commit fraud, or are otherwise guilty of naughty acts" with respect to the transaction acquire only voidable title. Tempur-Pedic Int'l, Inc. v. Waste to Charity, Inc., 483 F. Supp. 2d 766, 774 (W.D. Ark. 2007) (quoting James J. White & Robert S. Summer, Uniform Commercial Code § 3-12 (4th ed. 1995)); NEB. REV. STAT. U.C.C. § 2-403(1). Fresenius Kabi's own internal investigation has not indicated that any of its distributors sold Defendants the drugs, and thus the clear implication is that Defendants misappropriated them through improper, but undisclosed means. Defendants, therefore, have at best acquired voidable title and at worst void title. See Roberson v. Manning, 268 P.3d 1090 (Alaska 2012) (where goods are obtained through fraud or other nefarious means and the bad actor intends to re-sell the goods the title acquired is voidable; but when the bad actor intends to convert the goods to its own use the title acquired is merely void).

Further, the bona fide purchaser exception enumerated in UCC Section 2-403(1) is inapplicable. First, such an exception finds application only where the end user purchases the goods from one with voidable title. Second, and perhaps more importantly, the Defendants are not good faith purchasers. "Good faith" under the Uniform Commercial Code requires "honesty in fact in the conduct or transaction concerned." NEB. REV. STAT. U.C.C. § 1-201(20). Fresenius Kabi

communicated twice to the Defendants—in 2015 and 2016—that Fresenius Kabi's products are not to be sold to Defendants. The Defendants, with knowledge of the sale and use restrictions placed on any transfer of title in the products in question, acquired the same through improper and undisclosed means.

The NDOCS's own spokesperson has publicly represented that the drugs in question were purchased at the end of last year for $10,500, *after* the current administration had been twice notified of the restrictions. Joe Duggan, State Officials Say Nebraska Obtained Lethal Injection Drugs Legally, Omaha World-Herald (Mar. 13, 2018), https://www.omaha.com/news/legislature/state-officials-say-nebraska-obtained-lethal-injection-drugs-legally/article_ae950f0b-f479-559c-a78f-f0815ed53af5.html. In fact, Defendants have been attempting for many years to acquire drugs to circumvent the distribution-restriction terms of contracts for sale, causing one "livid" manufacturer of sodium thiopental to write a letter to the Chief Justice of the Nebraska Supreme Court. Stern, supra. The Defendants knew of the safeguards and distribution restrictions placed on the products by Fresenius Kabi and undertook to acquire the product anyway, either directly through fraud or deceit or with the assistance of a fraudulent or deceitful third party. In either event, the Defendants were not a good faith purchaser.

The Western District of Arkansas considered a similar situation in Tempur-Pedic Int'l, Inc. v. Waste to Charity, Inc., 483 F. Supp. 2d 766 (W.D. Ark. 2007). In that case, Tempur-Pedic ("TP") donated mattresses to Waste to Charity,

Inc. ("WTC"), with the express understanding that WTC distribute the mattresses to victims of Hurricane Katrina. Id. at 769. When TP learned WTC instead sold at least some of the mattresses, TP brought an action for fraud, breach of contract, and replevin. It also sought a TRO and preliminary injunction preventing the further sale or transfer of the goods. Id. at 768.

The district court granted the preliminary injunction, finding TP had established a probability of success in arguing the downstream purchasers never acquired good title to the mattresses. Id. at 775. Under § 4-203 of the Arkansas U.C.C., a person with "voidable title" to goods can only transfer good title to a "good faith purchaser for value." Id. at 774. The district court found TP met its burden of showing a likelihood of success in arguing WTC only had "voidable title" to the goods and that the subsequent purchasers were not good faith purchasers for value. Id. at 775. The Tempur-Pedic court observed that "voidable title passes to those who lie in the middle of the spectrum that runs from best faith buyer at one end to robber at the other." Id. at 774 (quoting White & Summer, Uniform Commercial Code § 3-12).

Fresenius Kabi has thus demonstrated a fair chance of proving the Defendants never obtained good title to the pharmaceuticals at issue and that Fresenius Kabi is entitled to their immediate return.

3. Fresenius Kabi Has A Fair Chance of Success on Its Interference with Interstate Commerce Claim

Fresenius Kabi has further demonstrated a probability of success on the merits regarding its claim for violation of the Commerce Clause. "The Commerce Clause provides that 'Congress shall have Power . . . [t]o regulate Commerce with

foreign Nations, and among the several states.' Although the Constitution does not limit the power of States to regulate commerce, we have long interpreted the Commerce Clause as an implicit restraint on state authority . . . ." United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 338, 127 S. Ct. 1786, 1992 (2007) (quoting U.S. Const., Art. I, § 8, cl. 3).

The Supreme Court has explained that restrictions on commerce are invalid where "the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." Pike v. Bruce Church, Inc., 397 U.S. 137, 142, 90 S. Ct. 844, 847 (1970). In this instance, Nebraska's circumvention of the very rules and supply controls that make the market for pharmaceutical drugs available creates a greater burden on interstate commerce than any putative local benefit.

KCL and Cisatracurium are designed, manufactured, and regulated to be life-*saving* drugs. The existence of a market for these drugs in adequate supply for their laudable purpose is entirely predicated on a federal system of testing and quality control. Defendants have operated entirely outside of this market, creating through procurement under their execution-protocol regulations a state-sanctioned black market in these goods. The use of KCL and Cisatracurium in a lethal injection protocol is not only not FDA approved, but diminishes the supply of these products for use in a manner which *is* FDA approved. This is underscored by the fact that KCL is currently included on the FDA's Drug Shortages list. FDA Drug Shortages, supra. Moreover, should the Defendants carry out the planned execution using Fresenius Kabi's products, the European

Union may implement regulation 1352/2011 with respect to propofol, which would further limit the supply of other life-saving products manufactured by the Company. [Weith Decl., ¶ 16]. Finally, the diminished supply of these drugs if allowed to be used for purposes of lethal injection may drive the market for them underground, allowing circumvention of FDA regulation.

On the other hand, the local benefit of utilizing this protocol is miniscule in comparison. No legitimate state interest is advanced by the Defendants' decision to employ this *particular* four-drug cocktail as opposed to any other lethal injection protocol (or any other method of execution, for that matter). To be clear, Fresenius Kabi takes no position on capital punishment and recognizes it to be the law of this State. [Silhavy Decl., ¶ 11; Meacham Decl., ¶ 17]. But the effect on interstate commerce of utilizing Fresenius Kabi's KCL and Cisatracurium in executing an inmate is demonstrably excessive in comparison to the benefits, if any, to the State of Nebraska.

Fresenius Kabi has therefore demonstrated a fair chance of success on the merits of its claim under the Dormant Commerce Clause.

4. Fresenius Kabi Has A Fair Chance of Success on Its Due Process Claim

Due process protects those property interests in which Fresenius Kabi has "a legitimate claim of entitlement." Bd. of Regents of State Colleges v. Roth, 408 U.S. 564, 577, 92 S. Ct. 2701, 2709, 33 L. Ed. 2d 548 (1972). Several of Fresenius Kabi's such interest are implicated here.

First, Fresenius Kabi has an interest in the KCL (and possibly the Cisatracurium) in Defendants' possession. As explained above with respect to

the replevin claim, Defendants do not have good title to these products and are holding them in violation of Fresenius Kabi's possessory interests. Surely, a possessory interest in tangible property is the quintessential type of property interest protected by due process. New Motor Vehicle Bd. Of Cal. v. Orrin W. Fox Co., 434 U.S. 1345, 1349 (1977) (rejecting due process claim and stating "The State of California was not seizing any existing tangible property interest of respondents by this Act"). Fresenius Kabi has just such an existing tangible property interest in its products held by Defendants.

Second, Fresenius Kabi has a property interest protected by due process in the goodwill of its business. "The goodwill of one's business is a property interest entitled to protection; the owner cannot be deprived of it without due process." Hardesty v. Sacramento Metro. Air Quality Mgmt. Dist., 307 F. Supp. 3d 1010, 1028 (E.D. Cal. 2018) (quoting Soranno's Gasco, Inc. v. Morgan, 874 F.2d 1310, 1316 (9th Cir. 1989)). In addition, "injury to existing business relationships . . . is generally sufficient to support a claim under procedural due process." Ward v. Anderson, 494 F.3d 929, 934 (10th Cir. 2007). "[S]ince one's business is property under [state] law, it cannot be injured or destroyed by the state without due process of law." Marrero v. City of Hialeah, 625 F.2d 499, 514 (5th Cir. 1980). Further, under the so-called "stigma plus" line of cases, Fresenius Kabi has an interest protected by due process in the tangible harms that will arise to it from the damage to its reputation by the use of its products in an execution. Id. at 515–16 ("Here, at least some of the defamatory statements are alleged to have resulted in injury not only to appellants' personal and

business reputations, but also to the goodwill of appellants' business, which, as we have determined, is a protected property interest." (footnote omitted)).

Whatever process might be due to Fresenius Kabi to give it a procedure through which it may protect its rights in its tangible property interest, goodwill, existing business relationships, and the tangible effects of harm to its reputation, it certainly must be more than the process which has been provided it by Defendants to date: none whatsoever. Despite Fresenius Kabi's repeated efforts to engage Defendants so as to present their claim to possession of their product and protection of their business interests, they have not had any opportunity to be heard. The Supreme Court "consistently has held that some form of hearing is required before an individual is finally deprived of a property interest." Mathews v. Eldridge, 424 U.S. 319, 333, 96 S. Ct. 893, 902, 47 L. Ed. 2d 18 (1976). Defendants threatened actions will deprive Fresenius Kabi of its property interests with no process at all, and therefore Fresenius Kabi has a fair chance of succeeding on its due process claim.

E. Enforcing Fresenius Kabi's Rights to Control Distribution of Its Products Benefits the Public Interest

Finally the district court must also weigh "whether granting the injunction would benefit the public interest." Pediatric Specialty Care, Inc. v. Ark. Dep't of Human Servs., 444 F.3d 991, 994 (8th Cir. 2006). As Fresenius Kabi has repeatedly stressed, adequate supply of its products serves the medical needs of its end users and the purpose of its supply-chain controls is to maintain the availability of those products.

In addition to circumventing Fresenius Kabi's contractual supply-chain controls, the Defendants also attempt to operate outside of the federal drug regulatory system. Federal law creates a "closed system" of drug distribution through careful regulation of the pharmaceutical supply chain via the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. § 301 *et seq.*, and the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.* The Food and Drug Administration (FDA) oversees the approval and extensive regulation of drugs entering the U.S. market under the FFDCA, consistent with its current mission of assuring the public that the medicines they use do no harm and actually work — that they are, in other words, safe and effective. Dabrowska, Agata and Thaul, Susan, How FDA Approves Drugs and Regulates Their Safety and Effectiveness, Congressional Research Service, 7-5700, R41983 (May 8, 2018), available at www.crs.gov.

Pharmacy, medicine, and health policy experts have announced growing concern with states' attempts to circumvent the extensive federal pharmaceutical regulatory system in surreptitiously, improperly, or fraudulently obtaining drugs for use in executions. Brief of Amici Curiae Pharmacy, Medicine, and Health Policy Experts in Support of Petitioner, Bucklew v. Precythe, 2018 WL 3546328 (U.S. July 2018). Especially where, as in Nebraska, "secrecy laws" attempt to shield a state's drug procurement practices from public view and scrutiny by regulatory authorities, the integrity of the U.S. drug supply chain and public health is threatened by the state's attempts to circumvent federal law. Id.; NEB. REV. STAT. § 83-967. This Court should not encourage state officials to seek drugs

for use in executions through such means that create dangers to patients and the public. As a recent academic article, published in the Journal of the American Pharmacists Association, put it:

> By circumventing federal law and purchasing medicines from non-FDA-approved suppliers, states are undermining the robust enforcement of chain of custody and pharmaceutical supply chain transparency in the US. A strong chain of custody through each step in the drug distribution system is the only way to control risks of contaminated or poor-quality products entering the US market. Without regulation, it is almost impossible to control which drug products move through a given supply channel and which end customers they reach.

Prashant Yadav, Rebecca Lynn Weintraub, et al., When Government Agencies Turn to Unregulated Drug Sources: Implications for the Drug Supply Chain and Public Health are Grave, J. AM. PHARM. ASSOC. (2018), available at https://doi.org/10/1016/j.japh.2018.06.019; see also [Clark Decl., Ex. D].

Additionally, because KCL is currently subject to a drug shortage, any quantity used in a lethal injection execution means an equivalent quantity is unavailable for use in proper care of a patient in need of that drug.

Here, the public has an undoubted interest in the safety secured by the very regulations and supply-chain controls Defendants have deliberately evaded.

F. Fresenius Kabi Has Shown That Its Request for Expedited Discovery Is Reasonable, Is Supported By Good Cause, and Is Narrowly Tailored to Obtain Information Relevant to Its Request for a Preliminary Injunction.

A motion for expedited discovery requires "a showing of reasonableness or good cause, taking into account the totality of the circumstances." Coram, Inc. v. Jesus, No. 8:10CV37, 2010 WL 584000, at *1 (D. Neb. Feb. 11, 2010). Fresenius Kabi has shown that Defendants possess its KCL. Given Defendants

past efforts to circumvent distribution restrictions, this raises a reasonable inference that Defendants may also possess Cisatracurium manufactured by Fresenius Kabi. As mentioned above, there are only three firms that sell Cisatracurium for medical use in the United States. [Silhavy Decl. ¶ 10]. Further, Defendants may have acquired other drugs manufactured by Fresenius Kabi not specifically within the four drugs to be used in the execution of Moore. Because Fresenius Kabi's request for an authorization for expedited discovery seeks only information needed to identify whether any of its drugs are in Defendants' possession, and is limited only to those drugs to be used in an execution by lethal injection, Fresenius Kabi "has narrowly tailored its request to obtain information relevant to preliminary injunction." Coram, 2010 WL 58400, at *1.

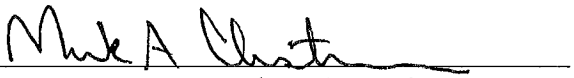
III. CONCLUSION

Fresenius Kabi does not take a stance on capital punishment. It does take a stance on its right to create and enforce contracts for the sale of its goods, the right to effect the medically legitimate purposes for which the FDA has approved its products, the right to protect its legitimate business interests, and the right to ensure that the patients whose lives depend on Fresenius Kabi's drugs have access to them. It respectfully prays, therefore, that this Court enter a temporary restraining order preserving the status quo until such time as the parties may be heard, and its motion for preliminary injunction be decided; that this Court authorize Fresenius Kabi to immediately discover information from Defendants to identify which of Fresenius Kabi's drugs are in their possession, including the quantities, lot numbers, inventory logs, and invoices for any and all substances

Defendants possess for the purposes of use in an execution by lethal injection; and that this Court enjoin Defendants from using its products in any execution and to impound those products until the merits of this dispute can be adjudicated.

Dated this 8th day of August, 2018.

FRESENIUS KABI USA, LLC,
Plaintiff

By: 

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CERTIFICATE OF SERVICE

I, Mark A. Christensen, hereby certify that on this 8th day of August, 2018, I electronically filed the foregoing document with the Clerk of the United States District Court using the CM/ECF system, which sent notification of such filing to the following:

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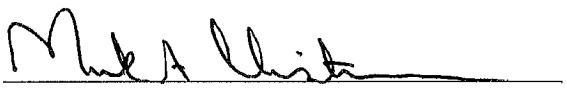

Mark A. Christensen

4821-4978-4175, v. 1